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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,083	09/11/2003	F. Mark Ferguson	SHP026.6	5916

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SPECIALIZED HEALTH PRODUCTS INC.
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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/660,083

Applicant(s)

FERGUSON ET AL.

Examiner

Christopher D. Koharski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40, 42-46 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 12-16, 23, 26, 33-34, 36-38 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 17-22, 27-32, 35, 40, 42-44, 46 and 48 is/are rejected.
- 7) ☒ Claim(s) 24, 25 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/14/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

Examiner acknowledges the remarks filed 11/22/2006 with no claims amendments. Currently claims 1-40, 42-46 and 48 are pending for examination in this application, with claims 12-16, 23, 26, 33, 36-38 and 45 being withdrawn from a previous election restriction.

Response to Arguments

Applicant's arguments, see remarks, filed 11/22/2006, with respect to the rejection of the claims 1-8, 10, 11, 17-22, 25, 27-30, 39-42, and 46-47 under Sircom et al. (5,328,482) have been fully considered and are persuasive. The rejection of these claims under Sircom et al. has been withdrawn.

Applicant's arguments filed 11/22/2006 concerning claims 43 and 48 have been fully considered but they are not persuasive. Regarding claims 43 and 48, Applicant's representative asserts as argued with respect to claims 1-8, 10, 11, 17-22, 25, 27-30, 39-42, and 46-47 Sircom et al. does not disclose binding members with drag inducing forces to facilitate inclination. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., drag inducing members for facilitating inclination) are not recited in the rejected claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, Examiner asserts that Sircom et al. clearly discloses a locking member (5) that engages the

needle with an end sensing member (109) that engages the needle and is capable of causing removal of the hub retainer from the catheter hub see (Figures 39-42) (see rejection below).

Upon further search and consideration this following additional double patenting rejection is applied.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 9/14/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 17-22, 27-32, 35, 40, 42 and 44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 17-20 of U.S. Patent No. 7,004,927, claims 1-5 and 22-24 of U.S. Patent No. 6,984,213, claims 1, 3, 8 and 10 of U.S. Patent No. 6,796,962 and claims 1, 7, 12 and 15 of U.S. Patent No. 6,902,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the current pending application are anticipated by the claims in the cited US patent.

Application claim 1 requires:

A medical needle shield apparatus comprising:

a shield being extensible from a retracted position to an extended position to enclose a distal end of a needle;

a binding member disposed within the shield and comprising binding surfaces that define an aperture configured for slidable receipt of the needle between the retracted position and the extended position,

the binding member including a retainer extending therefrom such that the retainer is engageable with the needle to prevent inclination of the binding member while the retainer is engaged with the needle;

the binding member further comprising one or more drag inducing

members that engage the needle during slidable receipt of the needle to create a drag force with the needle, the drag force and shield facilitating inclination of the binding member relative to a longitudinal axis of the needle once the retainer extends beyond the distal end of the needle such that the binding

surfaces engage the needle to prevent slidable movement of the needle in the extended position of the shield; and a hub retainer being configured to engage a catheter hub.

While patent claim 1 requires (7,004,927 for example):

A medical needle shield apparatus comprising: a shield being extensible from a retracted position to an extended position to enclose a distal end of a needle; and a binding member disposed within the shield and comprising binding surfaces that define an aperture configured for slidable receipt of the needle between the retracted position and the extended position, the binding member comprising a retainer extending therefrom such that the retainer is engageable with the needle to prevent inclination of the binding member while the retainer is engaged with the needle, the binding member further comprising at least one drag inducing member configured to engage the needle and create a drag force with the needle to cause inclination of the binding member relative to a longitudinal axis of the needle once the retainer extends beyond the distal end of the needle such that the binding surfaces engage the needle to prevent slidable movement of the needle in the extended position of the shield.

Thus it is apparent that the application claims are broader/narrower in scope than the patent claims and the subsequent patented independent and dependant claims of the above mentioned patents encompass application claims 1-11, 17-22, 27-32, 35, 40, 42 and 44. Following the rationale in *In Re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or

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narrower invention, Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting a terminal disclaimer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Sircom et al. (US 5,328,482).

Sircom discloses a needle shield (Figures 35-40, 53, and 53) including a shield (5), a binding member (101) with binding surfaces at (103) and a retainer at (109). The binding member including at least one drag inducing member at (110) that creates a drag force with the needle and creates friction with the needle, and a hub retainer being configured to engage a catheter hub at (119) (Figure 40), and a housing defining a blocking member would be (106) that can also act as a bearing. Additionally, Sircom et al. clearly discloses a locking member (5) that engages the needle with an end sensing member (109) that engages the needle and is capable of causing removal of the hub retainer from the catheter hub (119) see (Figures 39-42).

Allowable Subject Matter

Claim 24, 25 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

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